MAR 2 8 2001

K002705

510(k) Summary

Submitted by:

Baxa Corporation
13760 E. Arapahoe Road
Englewood, CO 80112

Contact Person: Karl Steineck
Phone: 303-617-2181
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Date Prepared: March 23, 2001

Manufacturing Facility:

Baxa Corporation
13760 E. Arapahoe Road
Englewood, CO 80112

Submitted Device:

Trade Name: Exacta-Mix 2400 Compounding System Administration set

Common Name: Administration sets

Device Classification: Class II

21 CFR § 880.5440 Intarvascular administration set

(a) Identification. An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.
(b) Classification. Class II (performance standards)

Predicate Device:

MicroMacro 23™ Compounder
510(k): K903159, Cleared November 7, 1990
Baxa Corporation
Englewood, CO

Product Description: The Exact-Mix 2400 compounding system Administration set, is designed to work in conjunction with the Baxa EM-2400 compounding system to quickly and accurately compound multi-ingredient sterile solutions by withdrawing requested amounts of source ingredients from their containers in a user specified sequence into a final container.

Intended Use: Exacta-Mix 2400 Compounding System Administration set, manufactured by Baxa Corporation, is a disposable component of a compounding device used in the pharmacy to compound multiple source ingredients into one final solution. This device is not intended for direct patient hook-up.

Statement of substantial equivalence-

The Exacta-Mix 2400 Compounding System Administration set is very similar to the MicroMacro 23 administration set in the following areas; intended use, operation, and function. The Exacta-Mix 2400 and the predicate device are both used to compound multiple source ingredients based on user-specified sequences and volumes.

A summary of the essential features between the MicroMacro 23 (predicate device) and the Exacta-Mix 2400 is contained in Table 1

Table 1

Comparison between the MicroMacro 23 and Exacta-Mix™ 2400 Compounding Systems

Feature	MicroMacro 23™ (Predicate Device)	Exacta-Mix™ 2400
Valve Controllers (disposable set)	Two	One
Sterile/NonPyrogenic disposable set	Yes	Yes

From Table 1 it can be seen that the two types of devices share the same basic features for fluid transfer.

Testing:

Laboratory testing was done to confirm the devices performance in relation to the predicate device.

Performance testing included the following:

1. Accurately deliver specified source volumes

3. Fluid/air leakage
4. Precipitant

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2001

Mr. Karl Steineck
Quality Systems Manager
Baxa Corporation
13760 East Arapahoe Road
Englewood, Colorado 80112

Re: K002705
Trade Name: Exacta-Mix™ 2400 Compounding System Administration Set
Regulatory Class: II
Product Code: LHI and NEP
Dated: December 11, 2001
Received: December 28, 2001

Dear Mr. Steineck:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to

comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Baxa Corporation

Exacta-Mix 2400 Compounding System Administration Set

Indications for Use Statement

Applicant: Baxa Corporation
510(k) Number (if Known) K002705

New Device Name: Exacta-Mix™ 2400 Compounding System Administration Set

Intended Use: Exacta-Mix 2400 Compounding System Administration set, manufactured by Baxa Corporation, is a disposable component of a compounding device used in the pharmacy to compound multiple source ingredients into one final solution. This device is not intended for direct patient hook-up.

Indications For Use: The Exacta-Mix 2400 compounding system administration sets, manufactured by Baxa Corportation, are ancillary devices used in conjunction with the Exacta-Mix 2400 compound device. The administration sets are used in the pharmacy to provide the fluid path for multiple source ingredients into one final solution.

Helena Ciccente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002705